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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,671	07/25/2008	Bradley T. Messmer	50425/245	1699
1912	7590	01/18/2011	EXAMINER	
AMSTER, ROTHSTEIN & EBENSTEIN LLP			AEDER, SEAN E	
90 PARK AVENUE				
NEW YORK, NY 10016			ART UNIT	PAPER NUMBER
			1642	
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			01/18/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/575,671	MESSMER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	SEAN E. AEDER	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 23 November 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 117-135 is/are pending in the application.  
 4a) Of the above claim(s) 121, 122 and 124-131 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 117-120, 123 and 132-135 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/3/08; 11/23/10</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

***Detailed Action***

***Election/Restriction***

The response filed on 11/23/10 to the restriction requirement of 9/27/10 has been received. Applicant has elected Group III and the following species: Set IV. Because Applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Due to an overlap in search, it is noted the following species has been rejoined:  
Set I.

Claims 117-135 are pending.

Claims 121, 122, and 124-131 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 117-120, 123, and 132-135 are currently under consideration.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 117-120 and 132-135 are rejected under 35 U.S.C. 102(b) as being anticipated by Valetto et al (Blood, 92(10) suppl. 1 part 1-2, 1998, abstract# 1784, page 431A).

Valetto et al teaches a method comprising determining whether B cell receptors on B-CLL cells from blood of a patient are encoded by Set I (see Abstract, in particular). Patients with such cells have a form of B-CLL susceptible to treatment or treatment of the patient has not eliminated the B-CLL cells. It is noted that the B-CLL patients of Valetto et al could be described as “preleukemic” for leukemias other than B-CLL. Due to the broad accepted definitions of “early leukemic state” and “frank leukemic state”, the B-CLL patients of Valetto et al could be described as in an “early leukemic state” or a “frank leukemic state”, depending on what an individual practitioner considers “early leukemic state” or a “frank leukemic state”.

Claims 117-119, 123, and 132-135 are rejected under 35 U.S.C. 102(b) as being anticipated by Fais et al (J. Clin. Invest., 1998, 102(8): 1515-1525).

**In regards to claim 117,** it is noted that the method does not require one to determine whether the entire polypeptide sequence of a B cell receptor on B-CLL cells is fully encoded by the recited antibody genes. Rather, the claims encompass methods wherein one is to determine whether any amount of a polypeptide sequence of a B cell receptor on B-CLL cells is encoded by the recited antibody genes.

Fais et al teaches a method comprising determining whether B cell receptors on B-CLL cells from blood of a patient are encoded by Set IV (see first row of Table II, in particular). Patients with such cells have a form of B-CLL susceptible to treatment or treatment of the patient has not eliminated the B-CLL cells. It is noted that the B-CLL patients of Fais et al could be described as “preleukemic” for leukemias other than B-

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CLL. Due to the broad accepted definitions of “early leukemic state” and “frank leukemic state, the B-CLL patients of Fasis et al could be described as in an “early leukemic state” or a “frank leukemic state”, depending on what an individual practitioner considers “early leukemic state” or a “frank leukemic state.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 117-120, 123, and 132-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Damle et al (Blood, 1999, 94(6): 1840-1847).

Damle et al teaches a method comprising determining V<sub>H</sub> and V<sub>L</sub> sequences encoding B cell receptors on B-CLL cells from blood of B-CLL patients (see page 1841,

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in particular). It is noted that the B-CLL patients of Damle et al could be described as “preleukemic” for leukemias other than B-CLL. Due to the broad accepted definitions of “early leukemic state” and “frank leukemic state”, the B-CLL patients of Damle et al could be described as in an “early leukemic state” or a “frank leukemic state”, depending on what an individual practitioner considers “early leukemic state” or a “frank leukemic state.

Damle et al does not specifically teach methods comprising determining whether the full lengths of B cell receptors on the B-CLL cells are fully encoded by Set I or Set IV.

However, one of ordinary skill in the art at the time the invention was made would have been motivated to identify prognostic indicators of B-CLL by determining all  $V_H$  and  $V_L$  sequences (including those that would be Set I and Set IV) of B cell receptors on B-CLL cells from blood of all patients with B-CLL and correlate the presence of each sequence with a prognosis for each patient because Damle et al teaches  $V_H$  and  $V_L$  sequences can be used as prognostic indicators of B-CLL (see left column on page 1841, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for identifying prognostic indicators of B-CLL by determining all  $V_H$  and  $V_L$  sequences (including those that would be Set I and Set IV) of B cell receptors on B-CLL cells from blood of all patients with B-CLL and correlate the presence of each sequence with a prognosis for each patient because Damle et al teaches  $V_H$  and  $V_L$  sequences can be used as prognostic indicators of B-CLL (see left column on page 1841, in particular). Therefore, the invention as a whole

would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

***Summary***

No claim is allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Sean E Aeder/  
Primary Examiner, Art Unit 1642